

REMARKS

Applicants have added new claims 45-47. These newly added claims are directed to elected Species II.

In the Office Action of July 17, 2001, the Examiner rejected claims 10-12 under 35 U.S.C. § 112, second paragraph, for reciting "the central body portion", which lacked antecedent basis in the claim. Claim 10 has been amended to remove the term "central." Therefore, Applicants respectfully request that this rejection be withdrawn.

The Examiner also rejected claims 10 and 11 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,281,205 to McPherson. Claim 12 was rejected under 35 U.S.C. § 103(a) as being unpatentable over McPherson in view of U.S. Patent No. 5,613,945 to Cai, et al.

Claim 10, as amended, is directed to an access port device including, *inter alia*, a "guidewire access site being disposed opposite the outlet." McPherson discloses an access port 10 having a base 22, a septum 26, and a core 18. As shown in Fig. 1, the septum 26 is located above a chamber 20 which includes an outlet 36. The septum 26 covers an opening 34 and allows insertion of a wire 14 into the chamber 20 and through the outlet 36. Since there is no guidewire access site opposite an outlet, the rejection of claim 10 under 35 U.S.C. § 102(b) should be withdrawn.

Claim 12 has been rewritten in independent form. Applicants respectfully disagree with the Examiner's rejection of this claim under 35 U.S.C. § 103(a). The Examiner asserted that it would have been obvious to modify McPherson with alleged "teachings of Cai . . . in order to prevent wear and tear on a drug needle access site by insertion of a guidewire". See paragraph 6 of the Office Action.

Applicants respectfully request that the Examiner reconsider the claim rejection under 35 U.S.C. § 103 and withdraw it because the cited references do not disclose or suggest the subject matter set forth in claim 12. In particular, there is no motivation or suggestion to modify McPherson with Cai, et al.

To establish a *prima facie* case of obviousness, three basic criteria must be satisfied. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify a reference or to combine references. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all the claim elements. See M.P.E.P. § 2143. Moreover, the requisite teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in Applicant's disclosure. See *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). See M.P.E.P. § 706.02(j).

The claim rejection under 35 U.S.C. § 103(a) should be withdrawn due to a lack of the required criteria for a *prima facie* case of obviousness. As an initial matter, there would not have been any motivation or suggestion that would have led one of ordinary skill in the art to combine the references as proposed by the Examiner.

McPherson is directed to a vascular access system for periodic infusion of medication, wherein a catheter portion of the system may be cleared without removal of the system from the patient. See col. 2, lines 3-9. The clearing of the catheter is accomplished by using a non-coring needle 16 and wire 14 inserted through a self-sealing septum 26. Since the self-sealing septum 26 is designed to pass a needle 16

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and wire 14 into the access port without allowing fluids to escape from the access port, there is nothing in McPherson to suggest that such a site would undergo "wear and tear" as apparently asserted by the Examiner. In fact, the principal objective of the McPherson reference, i.e., the removal of an obstruction in a catheter, would make it necessary for the septum 26 to be designed for repeated insertions of the needle 16 and wire 14 any time an obstruction occurs in the catheter.

Cai, et al. is directed to a dual port having two septums and two separate chambers. Each chamber includes a separate outlet tube allowing for different fluids to be introduced into the body. Since the McPherson reference does not have a pair of chambers, there is no reason one of ordinary skill in the art would look to any of the teachings of Cai, et al. Moreover, the Examiner's asserted motivation to combine the references (i.e., in order to prevent wear and tear on a drug needle access site by insertion of a guidewire) is not found in Cai, et al. Therefore, the Examiner has not made a case of *prima facie* obviousness and the rejection of claim 12 should be withdrawn.

Claims 45-47 have been added to add claims directed to certain aspects of the invention. All of these new claims are believed to correspond to the previously elected species.

Applicant respectfully requests the reconsideration of this application and the timely allowance of the pending claims.

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Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: October 17, 2001

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Application Number: 09/690,473
Filing Date: October 18, 2000
Attorney Docket Number: 6530.0020-02

APPENDIX TO AMENDMENT

Amendments to the Claims

10. (Amended) An access port device comprising:

a body portion having an upper body, a lower body attachable to the upper body, and a self-sealing septum between the upper and lower bodies;

an outlet for fixedly attaching a catheter to the [central] body portion; and

a guidewire entry site disposed in the upper body for inserting a guidewire into the septum and into said outlet, the guidewire entry site being disposed opposite the outlet.

12. (Amended) An access port device comprising:

a body portion having an upper body, a lower body attachable to the upper body, and a self-sealing septum between the upper and lower bodies;

an outlet for fixedly attaching a catheter to the body portion; and

a guidewire entry site disposed in the upper body for inserting a guidewire into the septum and into said outlet,

[The access port according to claim 10,] wherein the upper body has an access site disposed therein.

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